

The effect of diabetes education tailored to nurses in psychiatry

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Registration date 02/10/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/11/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Diabetes is more prevalent and insufficient treated among individuals with severe mental illness, and it is an important risk for heart diseases and premature death. On average individuals with severe mental illness die 15-20 years earlier than people without severe mental illness. The aim of the present study is to develop a diabetes education tailored to psychiatric nurses and investigate the effectiveness of the education to determine whether this will lead to better diabetes care among people with both severe mental illness and diabetes.

Who can participate?

People with severe mental illness and diabetes treated in one of the eight selected psychiatric outpatient clinics are all eligible to participate.

What does the study involve?

The study involves three consecutive days of diabetes education provided to all psychiatric nurses at four psychiatric out-patient clinics in Denmark. The effectiveness of the diabetes education is measured based on differences in quality of diabetes care in people with severe mental illness and diabetes treated at psychiatric outpatient clinics where all psychiatric nurses have participated in the diabetes education compared to psychiatric outpatient clinics where the psychiatric nurses have not participated in the diabetes education.

What are the possible benefits and risks of participating?

Benefits: For the psychiatric nurses to gain more knowledge and skills in diabetes treatment. For people with severe mental illness and diabetes, participating in the study, the benefit of participating is to gain better quality of diabetes care.

There is no risk of participating in the study as there is no extra blood test or other clinical test involved in this study. All the participants are asked to complete a baseline questionnaire and four follow-up questionnaires two years after the intervention. Moreover, the participants will give the research team access to data from the Danish Health care platform (medical journals) regarding their diabetes treatment and treatment of the psychiatric disease(s). The data will be stored in accordance with the GDPR regulations.

Where is the study run from?
Steno Diabetes Center Copenhagen, Denmark

When is the study starting and how long is it expected to run for?
April 2018 to March 2022

Who is funding the study?
1. The education department of Steno Diabetes Center Copenhagen
2. Jascha Foundation

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

The effectiveness of Diabetes Education tailored to nurses in PSYchiatry (DEPSY): a pragmatic non-randomised controlled cluster study

Acronym

DEPSY

Study objectives

The overall hypothesis is that the intervention, the diabetes education, will improve indicators of quality of diabetes care measured on individuals with diabetes and severe mental illness in the intervention cluster during 12- and 24-months follow-up after the intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was submitted to ethical approval (Region Hovedstaden, Center for Sundhed, De Videnskabssetiske Komiteer, Kongens Vaenge 2, 3400 Hillerod, Denmark; +45 38 66 63 95; vek@regionh.dk) but Ethical Committee assessed the study as a quality development study and was therefore not assessed by the ethical committee

Study design

Single-center interventional pragmatic non-randomized controlled cluster study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Diabetes and severe mental illness

Interventions

The intervention is a 3-day diabetes education tailored to psychiatric nurses in psychiatric outpatient clinics. The diabetes education is provided to all nurses employed at four psychiatric outpatient clinics, approximately 70 nurses in total. The education aims to improve the quality of

diabetes treatment for individuals with severe mental illness and diabetes. The overall aim of the education is to improve the nurses' diabetes knowledge and skills. The aim of the education is to provide the nurses with knowledge and skills which will give them the ability to identify and judge physical, mental and social changes for patients with severe mental illness and diabetes and support the patient in obtaining appropriate treatment of diabetes. The education is developed and conducted by the Department of Education at Steno Diabetes Center Copenhagen. The development of the intervention is based on a needs assessment lead by a team of both education and diabetes specialists (nurses, medical doctor, dietician and podiatrist) and health education researchers from the Department of Education to establish the nurses' current knowledge, skills and usual clinical practice. All nurses from the psychiatric outpatient clinics in the intervention group will participate in the intervention from February 2019 until December 2019.

The control group will receive standard of care, as provided by the Danish Health Care System which provides universal care to all.

The intervention group and control group were allocated in accordance with the regional organisation of psychiatric wards where it was possible to deliver the intervention.

Intervention Type

Behavioural

Primary outcome(s)

1. Number of measurements and change in HbA1c levels collected two years prior to the intervention (baseline) and every 6 months 2 years after the intervention
2. Patient-reported outcomes measured in questionnaires collected one time before the intervention (baseline) and once every 6 months 2 years after the intervention. The patient-reported outcomes are based on the following scales SDSCA, PAID5, DAWN2 (tailored to people with both severe mental illness and diabetes), PACIC (tailored to people with both severe mental illness and diabetes), CARE (tailored to people with both severe mental illness and diabetes), WHO5 and SF36 and two new questions has been developed for the present study: On a scale from 1 to 10 how much does diabetes impact your everyday life?
How relevant is it to receive diabetes-related support from your psychiatric nurse from the psychiatric outpatient clinic?

Key secondary outcome(s)

Measured two years before the intervention and every 6 months 2 years after the intervention:

1. Change in number of measured lipids, urine albumin /creatinine ratio, blood pressure, weight and BMI collected from electronic patient journals
2. Change in levels of lipids, urine albumin/creatinine ratio, blood pressure, weight and BMI collected from electronic patient journals
3. Change in number of prescriptions on diabetes-related medicine (glucose-, lipids and blood pressure lowering medicine) collected from electronic patient journals
4. Change in proportion of patients screened for diabetes complications collected based on questionnaires

Completion date

31/03/2022

Eligibility

Key inclusion criteria

1. Individuals diagnosed with diabetes and severe mental illness
2. Treated in one of the eight psychiatric outpatient clinics in the recruitment period
3. Aged ≥ 18 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

107

Key exclusion criteria

1. Patients without diabetes
2. Patients not in the psychiatric outpatient clinics
3. Patients who do not wish to participate

Date of first enrolment

30/08/2018

Date of final enrolment

01/06/2019

Locations**Countries of recruitment**

Denmark

Study participating centre

Psychiatric Outpatient Center Ballerup

Bygning 28A

Maglevænget 2

Ballerup

Denmark

2750

Study participating centre
Psychiatric Outpatient Center Gladsaxe
Gladsaxe Møllevej 15, 1.sal
Søborg
Denmark
2860

Study participating centre
Psychiatric Outpatient Center Hillerød
Dyrehavevej 48
Hillerød
Denmark
3400

Study participating centre
Psychiatric Outpatient Center Helsingør
Esrumvej 143
Helsingør
Denmark
3000

Study participating centre
Psychiatric Outpatient Center Bispebjerg-Brønshøj
Møntmestervej 17
København NV
Denmark
2400

Study participating centre
Psychiatric Outpatient Center Frederiksberg og Vanløse
Nimbusparken 24
Frederiksberg
Denmark
2000

Study participating centre
Psychiatric Outpatient Center Indre by og Østerbro
Strandboulevarden 96
København Ø
Denmark
2100

Study participating centre
Psychiatric Outpatient Center Nørrebro
Griffenfeldsgade 46
København N
Denmark
2200

Sponsor information

Organisation
Steno Diabetes Center

ROR
<https://ror.org/03w7awk87>

Organisation
Jascha Foundation

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Steno Diabetes Center Copenhagen - Education Department

Funder Name
Jascha Foundation

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to national and regional data protection guidelines it is not possible to share the data even though the data is pseudonymised

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/11/2024	19/11/2024	Yes	No
Other publications	528		17/11/2023	Yes	No
Other publications	652		17/11/2023	Yes	No
Other publications	Observational cross-sectional study	25/01/2022	17/11/2023	Yes	No